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EXAMINER	
YEH, JENNER	

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3763	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,990	GONON, BERTRAND	
	Examiner	Art Unit	
	JENNER YEH	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 July 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/6/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Objections

2. Claims 30, 45, 48 and 57 are objected to because of the following informalities:

In the second limitation of claim 30 regarding a secondary derivation branch 15, the principal fluid circuit branch 4 controlled by a second isolation valve 23 should be changed to secondary derivation branch 5 controlled by a second isolation valve 23 (Please see Figure 1 in Applicant's disclosure). Appropriate correction is required.

RE claim 45, there is insufficient antecedent basis for the limitation "the anti-return flow control device". Examiner suggests changing the claim to "an anti-return flow control device".

Claim 48 is written in an improper dependent form. Examiner suggests rewriting claim 48 such that it is an independent claim or making claim 48 depend on claim 49. For examination purposes, Examiner will consider claim 48 to be dependent on claim 49 since both claims 48 and 49 are drawn to a method of generating a sequence of jet pulses.

Claim 57 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 57 depends on claim 49 and cites a limitation that an active product is used in microscopic doses; however, claim 49 already cites the limitation that a microscopically dosed impulse of active product is to be delivered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 52 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claim 52, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 30-32 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gonon (WO 00/56232) in view of Wunsch (US 4559036).

8. RE claim 30, Gonon disclose an apparatus for injecting an active product comprising a reserve of working fluid 3 pressurized by a pressurized liquid generator 2, a handpiece 5 terminating in an active extremity 8 that comprises an outlet means 10 for a pressurized jet of working liquid and a jet of active product wherein a principal fluid circuit branch connecting a reserve of working liquid 3 to the handpiece 5 is parallel to a secondary derivation branch designed to contain active product 18 and independent control of the flow through the secondary and principal fluid branches is achieved through multiplexing means 26 (abstract and title figure).

Gonon discloses the multiplexing means 26 is a means for switching or mixing the working liquid with the active product (abstract) but does not disclose the particulars of the

multiplexer means and does not disclose the principal fluid circuit branch and the secondary derivation branch controlled by a first and second isolation valve, respectively, where the secondary derivation branch is fluidly isolated from the principal fluid circuit branch. Valved switching systems for multiple reserves of fluid and with multiplexing means to control the sequence of flow are well known in the art. Wunsch teaches an apparatus for sequentially delivering multiple intravenous supplies to a patient where multiple fluid circuit branches 16, "supply tube", are located parallel to each other (Figure 1; all supply tubes hang downwards and are generally perpendicular to the horizon), connect a fluid supply 15 to a handpiece 19, "catheter", and are controlled by isolation valves 40 (Figures 1 and 2; Col 3, lines 16-42). Wunsch further teaches multiplexing means for independent control of the valves according to predetermined parameters (Col 3, lines 43-68).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute Gonon's multiplexing means with the switching injection device of Wunsch, to achieve the predictable result of taking multiple fluid inputs and providing switching means to independently control the fluid flow.

9. RE claim 31, Wunsch discloses the multiplexing means can be controlled according to any predetermined parameters previously stored and selected by a user (Col 3, lines 49-54 and Col 4, lines 11-17 and Col 10, lines 18-26).

10. RE claim 32, Gonon discloses the reserve of working liquid 3 is a flexible plastic pouch containing the working liquid and the generator of pressurized liquid 2 is an enclosure

surrounding the reserve of working liquid which is filled with neutral gas until the reserve is pressurized sufficiently to compress the pouch and pressurize the liquid (Col 8, lines 7-22).

11. RE claim 36, Gonon discloses the apparatus further comprising a suction system 12, connected to a vacuum source 13 (abstract and Title Figure).

12. Claims 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gonon (WO 00/56232) and Wunsch (US 4559036) and further in view of Chow et al (US 6692466).

13. RE claims 33-35, Gonon discloses the active extremity 8/16, "tube" can be introduced and guided into a catheter (Col 10, lines 14-31) and disclose that injection devices may be carried by or integrated into catheters (Col 3, lines 9-18). It would have been obvious to one of ordinary skill at the time the invention was made for Gonon to modify the active extremity such that it is a catheter for the purpose of injecting substances into vasculature (Col 15, line 28 to Col 16, line 18). Chow et al disclose a catheter with a retractable needle (title, abstract and Col 6, lines 23-39).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute Gonon's active extremity with a retractable needle catheter, as taught by Chow, to achieve the predictable result of delivering therapeutics into vasculature.

14. Claims 37, 39 and 40 are are rejected under 35 U.S.C. 103(a) as being unpatentable over Gonon (WO 00/56232) and Wunsch (US 4559036) and further in view of Pastrone et al (US 5496273).

15. RE claim 37. Gonon in view of Wunsch disclose all the claimed elements, as discussed above, but do not disclose an anti-return flow control device located at an outlet of the principal branch. Use of anti-return flow control devices or one-way check valves is well known in the art for maintaining sterility and ensuring proper flow path. Pastrone et al teach a drug infusion system where multiple drug supplies are delivered and one-way check valves 38/40/42 are located at the outlets of multiple drug supply tubes 18/20/22 before the multiple fluid flow paths are processed and output (Figure 1; Col 2, lines 27-35).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Gonon's apparatus to include an anti-return flow control device at an outlet of the principal fluid circuit branch, as taught by Pastrone, because it is well known in the art and for the purpose of preventing unwanted backflow of fluids.

16. RE claims 39 and 40, Gonon and Wunsch in view of Pastrone et al disclose all the claimed elements, but do not disclose the check valves located near to the fluid branch isolation valves and do not disclose the check valves integrated within the second and first isolation valves.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to place the check valves near the isolation valves since it has been held that

rearranging parts of an invention involves only routine skill in the art, and it would have been obvious to one of ordinary skill in the art at the time the invention was made to make both the check valves and isolation valves integral since it has been held that use of a single piece construction is a matter of engineering design choice.

17. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gonon (WO 00/56232) in view of Sertic et al (US 5116316).

18. RE claim 30, Gonon disclose an apparatus for injecting an active product comprising a reserve of working fluid 3 pressurized by a pressurized liquid generator 2, a handpiece 5 terminating in an active extremity 8 that comprises an outlet means 10 for a pressurized jet of working liquid and a jet of active product wherein a principal fluid circuit branch connecting a reserve of working liquid 3 to the handpiece 5 is parallel to a secondary derivation branch designed to contain active product 18 and independent control of the flow through the secondary and principal fluid branches is achieved through multiplexing means 26 (abstract and title figure).

Gonon discloses the multiplexing means 26 is a means for switching or mixing the working liquid with the active product (abstract) but does not disclose the particulars of the multiplexer means and does not disclose the principal fluid circuit branch and the secondary derivation branch controlled by a first and second isolation valve, respectively, where the secondary derivation branch is fluidly isolated from the principal fluid circuit branch. Valved switching systems for multiple reserves of fluid and with multiplexing means to control the

sequence of flow are well known in the art. Sertic et al teach a system capable of mixing and switching between a fluid source 14 and a source of medicament 42, "vial" (abstract; Figure 1), having multiplexing means settable according to desired parameters, "computer" (Col 10, lines 33-40 and comprising a primary fluid branch 15 controlled by an isolation valve 18 and a secondary derivation branch 24/26 controlled by an isolation valve 32 (Figure 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute Gonon's multiplexing means with the switching and mixing injection apparatus of Sertic, to achieve the predictable result of taking multiple fluid inputs and providing switching means to independently control the fluid flow.

19. Claims 38, 41, 42 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gonon (WO 00/56232) and Sertic et al (US 5116316) and further in view of Dzwonkiewicz (US 5807312).

20. RE claim 38, Gonon in view of Sertic et al disclose all the claimed elements, as discussed above, and Sertic et al disclose two isolation valves 32 and 34 located at two extremities of the secondary derivation branch 24/26 (Figure 1). However, Gonon in view of Sertic et al do not specifically disclose anti-return flow control devices attached at two extremities of the secondary derivation branch. One-way check valves are well known in the art and it would be obvious to one of ordinary skill in the art to place check valves at locations where preventing a reflux is desirable. Further, Dzwonkiewicz teaches a pump apparatus where there is a primary fluid path and an adjunct fluid source, "bolus syringe", that is connected with the primary fluid path and

can be opened to deliver the adjunct fluid with the primary fluid or closed (Figure 1; abstract). Dzwonkiewicz teaches two check valves 60 and 140 located at the inlet and outlet, respectively, of the connection point at which the adjunct fluid source connects with the primary fluid path and teaches that the check valves prevent unwanted backflow (Figure 1; Col 6, lines 7-15 and Col 6, line 48 to Col 7, line 9).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Gonon's apparatus to include two anti-return flow control devices at the inlet and outlet of the secondary derivation branch, as taught by Dzwonkiewicz, for the purpose of preventing unwanted backflow of fluid.

21. RE claims 41 and 42, Gonon in view of Sertic et al disclose all the claimed elements, as discussed above, and Gonon discloses the apparatus comprising a reserve of active product 18 (abstract and Title figure) but do not disclose the reserve of active product connected to the secondary derivation branch by a charge valve with two or three tracks. Sertic et al disclose a reserve of active product 42, "vial", having a connection means that controls flow of fluid into and out of the vial (Col 9, lines 30-40). Dzwonkiewicz also teaches a connection means that controls flow of fluid into and out of a fluid reserve, "syringe" where the connection means is a three-way stopcock that can be adjusted to allow three different fluid flow paths (Col 12, line 61 to Col 14, line 6; See Figures 5a - 7b for a pictorial of the three positions: Flow, Figure 5a, where the syringe is closed; Draw, Figure 6a, where fluid enters the syringe; and Bolus, Figure 7a, where fluid exits the syringe).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute Sertic's vial connector with a three-way stopcock, as taught by Dzwonkiewicz, to achieve the predictable result of controlling entry and exit of fluid into and out of a fluid reserve.

22. RE claim 46, Gonon in view of Sertic et al disclose all the claimed elements, as discussed above, but do not disclose the isolation valves comprising a cam-shaped roller which, when closed, crushes the tube from the outside. Roller clamps are well known in the art, and it would have been obvious to one of ordinary skill in the art to use a roller clamp as an isolation valve. Further, Dzwonkiewicz teaches a roller clamp as a fluid control means to restrict or allow flow (Col 7, lines 43-61; Figure 1).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute Sertic's isolation valve with roller clamps, as taught by Dzwonkiewicz, because roller clamps are well known in the art and to achieve the predictable result of opening and closing a tube.

23. Claims 43 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gonon (WO 00/56232) and Sertic et al (US 5116316) and further in view of Heilman et al (US 5569181).

24. RE claim 43, Gonon in view of Sertic et al disclose all the claimed elements, as discussed above, but do not disclose the secondary derivation branch comprising a tubular portion serving as a reserve that is calibrated for one precise dose of active product. Heilman et al teach a device

for mixing fluids and subsequently delivering a dosage of the mixed fluid to a patient (Col 3, lines 59-65 and Col 4, lines 22-25) and teach that a dosing unit is determined by a length of tubing (Col 5, lines 36-43).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Sertic's fluid tubes to comprise a tubular portion that serves as a reserve calibrated for one precise dose of active product, as taught by Heilman, for the purpose of delivering precise dosage amounts of drugs to a patient. It would have been obvious to one of ordinary skill in the art to place the precisely calibrated tubular portion in the secondary derivation branch as a matter of obvious engineering design choice.

25. RE claim 47, Gonon in view of Sertic et al disclose all the claimed elements, as discussed above, but do not disclose elements on the fluid circuit that could become contaminated to be sterile, disposable, single-use elements. The usage of disposable, single-use medical products is well known in the art as a means of preserving sterility and hygiene. Further Heilman et al teach disposable units as a means of maintaining sterility (abstract).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Sertic's tubes such that they are disposable and single-use, as taught by Heilman, for the purpose of maintaining a hygienic environment and sterile product use for each patient.

26. Claims 44-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gonon (WO 00/56232) and Sertic et al (US 5116316) and further in view of Massengale et al (US 6981967).

27. RE claims 44 and 45, Gonon in view of Sertic et al disclose all the claimed elements, as discussed above, but do not disclose the secondary derivation branch having a tubular portion with a reduced interior diameter that is a restrictor and the restrictor located at an inlet to the secondary derivation branch before an anti-return flow control device. Massengale et al teach an injection apparatus with two parallel fluid branches where fluid is supplied through a fluid reserve (Figure 1, abstract) and teach a tubing of reduced diameter that acts as a restrictor to allow fluid to flow from the fluid reserve into a fluid branch at a controlled and predictable rate (Col 4, lines 6-10). The restrictor is located at an inlet to a second fluid branch (Figure 1) and is located before a check valve (Figure not shown; See Col 6, lines 23-56) where the check valve further serves to regulate flow control and prevent wanted reflux.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Sertic's apparatus to include a reduced diameter tubing restrictor and a check valve, as taught by Massengale, for the purpose of providing a controlled and predictable fluid flow rate and for better regulation of flow control.

28. **Claims 48-52, 57 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gonon (WO 00/56232) and Sertic et al (US 5116316) and further in view of Iriguchi et al (US 4059107).**

29. RE claims 49 and 57, Gonon in view of Sertic et al disclose all the claimed elements, as discussed above, and Gonon discloses a method of generating a sequence of liquid jets where a sequence consists of sequential impulses of a working fluid and a treatment product (Col 7, lines 19-25) and discloses the expulsion of the working fluid operates to cut or dissect tissue (Col 9, lines 11-17). Gonon does not disclose the sequence consisting of at least one impulse of pressurized working liquid followed by a microscopically dosed impulse of active product.

Iriguchi et al teach a two-step method of injection that involves first injecting an impulse of a highly pressurized liquid to perforate skin and second injecting an impulse of a lower pressure liquid that has a therapeutic effect (Col 1, lines 39-51). Iriguchi et al teach that the two step method helps to lessen the pain of an injection for the patient (Col 1, lines 48-51).

While Iriguchi et al only uses one liquid in his two-step method, it would have been obvious to one of ordinary skill in the art to modify Gonon's method of sequential pulses to include a first highly pressurized impulse of working fluid and afterwards, a second impulse of active product, as taught by Iriguchi, for the purpose of minimizing patient pain during an injection. It would have been obvious to one of ordinary skill in the art at the time the invention was made to expel a microscopically dosed impulse of active product if micro-dosing were the desired dosage amounts, and Sertic et al disclose the apparatus is capable of micro-dosing (Col 7, lines 14-15).

30. RE claim 48, as best interpreted, Iriguchi et al disclose a method of forming a hollow injection channel after blasting a jet of a pressurized liquid and afterwards injecting active product into the injection channel (Col 1, lines 39-51 and Col 2, lines 11-17).

31. RE claim 50, Gonon in view of Sertic et al and Iriguchi et al disclose opening the first isolation valve to generate an impulse of an appropriate quantity of pressurized working liquid and then in a later phase, opening the second isolation valve to generate an impulse formed of the desired quantity of active product. Iriguchi et al disclose the method of generating an impulse of pressurized working liquid followed by an impulse of active product, as discussed above (Col 1, lines 39-51) and Sertic et al disclose the first and second isolation valves can be programmed in whatever sequence necessary to perform the desired operation (Col 10, lines 33-40). Since the first and second isolation valves 18/32 control the flow of working liquid 14 and active product 42, "vial", (Figure 1), it would have been obvious to one of ordinary skill in the art to program Sertic's pump apparatus such that the first isolation valve is opened first to expel working liquid and the second isolation valve is opened second to expel active product for the purpose of carrying out the operation of Iriguchi's method.

32. RE claim 51, Iriguchi et al disclose the pressure pulse of active product essentially corresponds to the pressure pulse needed to form the initial opening in the tissue (Col 1, lines 39-51; use of the term "essentially" is indefinite and a pressure of 100 Kg/cm^2 can be considered to essentially correspond to a pressure of 120 Kg/cm^2 since the second pressure depends on the first).

33. RE claim 52, Iriguchi et al disclose the pressure pulse of active product is less than the pressure pulse needed to form the initial opening in the tissue (Col 2, lines 11-15).

34. RE claim 58, Gonon in view of Sertic et al disclose the method further comprising the steps of charging the apparatus with active product; preparing one or more blasts by successively disposing packets of fluid in the appropriate order and quantity and placing them in blasting position at the active distal extremity of the apparatus just before the outlet orifice; placing the active distal extremity of the apparatus in blasting position; and performing at least one blast of a series of liquid jets (Col 13, lines 13-26; Gonon discloses delivering a sequence of pressurized pulsed liquid jets of active product. It would have been obvious to one of ordinary skill in the art that delivering an active product from a reserve of active product first requires the apparatus to be filled with the active product. Further, each pressurized pulse may be considered as a packet of fluid, which delivered in sequence would place each packet, or pulse, at the distal extremity before the outlet orifice. Placing the active distal extremity of the apparatus in blasting position, or in the desired treatment location, would have been obvious to one of ordinary skill in the art).

Gonon does not disclose purging air from the apparatus in order to fill it with working liquid since Gonon does not disclose the particulars of the apparatus. Sertic et al teach that use of his apparatus includes purging air from the apparatus so that it may be filled with working fluid (Col 10, lines 1-16; ie. A first step involves air forced through a cannula and exiting, and a second step involves working fluid entering the cannula).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Gonon's method to include a purging air step, as taught by Sertic, for the purpose of preparing the apparatus for delivery.

35. **Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gonon (WO 00/56232), Sertic et al (US 5116316) and Iriguchi et al (US 4059107) and further in view of Talonn (US 4857056).**

36. RE claim 53, Gonon in view of Sertic et al and Iriguchi et al disclose all the claimed elements, as discussed above, but do not disclose the impulse of active product followed by another impulse of pressurized working fluid. Talonn teaches a method of injection delivery and teach injecting a flush solution after injection of an active product where the flush solution step is added to insure complete delivery of the active product (Col 2, lines 18-36).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Gonon's method to include the step of injecting working liquid after injection of the active product, as taught by Talonn, for the purpose of flushing out the apparatus and insuring the entire dose is delivered to a patient.

37. **Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gonon (WO 00/56232), Sertic et al (US 5116316) and Iriguchi et al (US 4059107) and further in view of Malamud et al (US 5928195).**

38. Re claim 54, Gonon in view of Sertic et al and Iriguchi et al disclose all the claimed elements, but do not disclose establishing the quantities of working liquid and active product to be delivered by fixing the opening time of each of the first and second isolation valves. Malamud et al teach a method of drug delivery where valves are electronically controlled to effect fluid and drug delivery and the dosage of a drug is predetermined by the amount of time a valve is kept open (abstract).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Gonon's method of drug delivery to include the step of controlling drug dosage by controlling the opening and closing times of the isolation valves, as t aught by Malamud, for the purpose of metering precise dosage amounts.

39. **Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gonon (WO 00/56232), Sertic et al (US 5116316) and Iriguchi et al (US 4059107) and Malamud et al (US 5928195) and further in view of Sage, JR (US 6582393).**

40. RE claim 55, Gonon in view of Sertic et al, Iriguchi et al and Malamud et al disclose all the claimed elements, as discussed above, but do not disclose varying the opening and closing times of the first and second isolation valves as a function of the viscosity of the liquids. Sage, JR teaches a drug delivery system where the drug delivery device changes the amount of time a fluid valve is open or closed based on the viscosity of the fluid being delivered (claim 8). Sage, JR teaches that the drug delivery device provides a more constant flow rate or more accurate

dosage because the drug delivery device compensates for any unforeseen changes in the fluid to be delivered, such as a change in viscosity (abstract and Col 9, lines 22-41).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Gonon's method to include a step of varying the opening and closing time of the first and second isolation valves such that the times vary as a function of the viscosity of the liquids, as taught by Sage, JR, for the purpose of ensuring a more accurate dosage delivery, regardless of environmental changes.

41. **Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gonon (WO 00/56232) and Sertic et al (US 5116316) and further in view of Malamud et al (US 5928195).**

42. RE claim 56, Gonon in view of Sertic et al disclose all the claimed elements, as discussed above, and Gonon discloses a method of generating a sequence of liquid jets where the working liquid and active product are mixed before being delivered (Col 12, line 32 to Col 13, line 7). As discussed above, Sertic et al disclose programming the opening and closing of the first and second isolation valves based on a desired drug injection operation (Col 10, lines 33-40). It would have been obvious to one of ordinary skill in the art at the time the invention was made to open both the first and second isolation valves of Sertic to allow both working liquid and the drug to flow for the purpose of performing the method of mixing working liquid and active product as taught by Gonon.

Gonon in view of Sertic et al do not disclose the amounts of working liquid and active product determined by regulating the opening and closing time of each of the first and second

isolation valves. As discussed above, Malamud et al teach metering a precise dose of liquid by controlling the amount of time a fluid valve is opened or closed (abstract).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Gonon's method to fix the amount of time the first and second isolation valves are open, as taught by Malamud, for the purpose of delivering a predetermined amount of working liquid and active product.

Conclusion

43. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Slate et al (US 2002/0055707) and Vaillancourt (US 5188603) disclose methods of injecting a highly pressurized dose of fluid followed by a lower pressurized dose of fluid.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNER YEH whose telephone number is (571)270-7836. The examiner can normally be reached on Monday-Thursday, 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571)272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. Y./
Examiner, Art Unit 3763

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